REMARKS

In the Office action of April 30, 2008, claims 1, 2, 5 to 12 and 17 to 23 are pending of which claims 1, 2, 5 to 12 and 17 to 23 were rejected.

In particular:

- Claims 1, 9, 10 and 12 were rejected under 35 USC 102(b) as being anticipated by Brown et al (US 5,769,887).
- Claims 2, 5, 6, 8, 17 to 20, 22 and 23 are rejected under 35 USC 103(a) as being unpatentable of Brown et al (US 5,769,887) in view of Aiba et al (US 6,221,096).
- Claims 7 and 11 are rejected under 35 USC 103(a) as being unpatentable of Brown et al (US 5,769,887) in view of Greenberg et al (US 2002/0198587).
- Claim 21 is rejected under 35 USC 103(a) as being unpatentable of Brown et al (US 5,769,887) in view of in view of Aiba et al (US 6,221,096) and further in view of Greenberg et al (US 2002/0198587)

DISCUSSION

As has been discussed in previous responses the independent apparatus claims 1, 10, 17 of this present application each claim a prosthesis which is specifically designed for the treatment, by intraluminal placement, of aortic dissection caused by a rupture in the wall of an aorta of a patient. While these functional features are not specified in the claims they are present in the structural features claimed. For this purpose the prosthesis has a specific claimed structure which is not disclosed or suggested in the prior art references raised by the Examiner. The prosthesis has a number of self expanding stents flexibly linked together by flexible links with at least one of the stents having a biocompatible graft material cover defining a covered portion and the balance defining an uncovered portion.

The importance of the covered portion is that it can be positioned to close off

the rupture in the wall of a lumen which occurs with an aortic dissection.

The uncovered portion is equally important as once deployed it provides continuous steady pressure on the wall of the lumen adjacent to, and extending away from, the rupture to deflate the false lumen caused by a aortic dissection. It may take some time, days or weeks, for the false lumen to deflate and during this time the steady pressure of a self expanding stent assists with this deflation. The importance of the use of self expanding stents for the provision of this pressure to deflate the false lumen resulting from an aortic dissection is discussed on page 9 of the specification in the paragraph which discusses Figure 5.

We refer the examiner to the portion of page 9 which states:

> " *The stents provide gradual pressure on the wall of the lumen to close the false lumen and open up the true lumen.*"

It should be particularly noted by the Examiner that the claim defines self-expanding stents as these are elastic and will tend to provide continuous pressure against the wall of a lumen after deployment.

The claim also specifies that the self expanding stents are linked together by flexible links. A link is not a solid bar rigidly fixed to items at each end of it but is connected to the items each side of it so that there can be relative movement, such as for instance a link in a chain as is shown in Figure 5 of the present application or a portion of suture material such as shown in Figure 6 of the present application. The flexible links are important to allow various parts of the uncovered portion to expand a different rates as the false lumen deflates and to also to allow for bends or curves in the descending aorta, that region of the aorta in which an aortic dissection often occurs.

Balloon expandable stents with solid integral connections between adjacent circumferential parts of the stent cannot be used for such a process because one part cannot expand separately than other along the length. When they are instantly expanded to their full size using a balloon a rapid expansion could rupture the wall of

the aorta in the region of the false lumen with fatal results. They are not designed for nor do they provide continuous pressure.

The use of uncovered stents to provide pressure on the wall of the lumen adjacent to an extending away from the rupture to deflate the false lumen is also important because in this region there may be branch vessels such as the mesenteric arteries extending from the aorta and an uncovered stent will not cause occlusion of these branch vessels. Occlusion could result in partial paralysis in a patient.

It is also important that the prosthesis of the present invention is a single component so that it can be quickly deployed when necessary. A significant number of aortic dissections are caused by accidental trauma and speed is of the essence in treatment. Having only a single component to deliver to the rupture site in the aorta means that treatment can be achieved quickly.

Hence there are several important features for a prosthesis of the present invention. For treatment of aortic dissection the prosthesis of the present has:

- A covered portion with a self expanding stent inside to close off the initial rupture
- An uncovered portion formed from a series of self expanding stents to provide pressure on the wall of the false lumen
- Flexible links between the self expanding stents to allow for variable deflation and curves.

We submit that none of the cited references whether taken singly or in any combination teach or suggest this set of features.

Now looking at each of the references in detail:

Brown et al (US 5,769,887)

The reference Brown et al teaches an unstented tubular graft with a single

balloon expandable exposed stent fastened to one end of the graft material. The specification says that exposed stent can be balloon expanded or self expanding but there is no teaching or suggestion how an self expanding stent could be used nor that there are a number of stents linked together by flexible stents. The examiner has referred us to several items in Brown but we submit that none of these teach the present prothesis. These are:

- Item 22 in Figure 4c – This is a balloon expandable stent not a self expanding stent.
- Item 23 in Figure 4c – These are defined as tie bars (column 4 line 24), but they are not flexible links. The portions tie bars join the circumferential parts of the stent but this does not mean that they are links. Links, as discussed above have a different meaning.
- Item 12 graft covering one stent 22b – In a balloon expandable stent the item as is shown in Figure 4c the item 22b is not a stent but one end of a stent. Further the whole of the graft material does not have a self expanding stent within it so that it could not be used to close off a rupture in the aorta wall.

Hence Brown does not teach any of the essential features as enumerated above.

We note the Examiners comments that in the absence of any teaching that the tie bars of Brown et al are not flexible then they are assumed to be flexible. We submit strongly that this is a mis-interpretation of US Patent Law. There has to be a positive teaching or suggestion to support such an interpretation. There is not in Figure 4c to which the Examiner has drawn our attention. We note that the Examiner has made the statement that "the device of Brown is capable of performing each of the three functions". As we have discussed above it is clearly of a structure that would prevent it from doing so.

Hence Brown does not teach any of the essential features as enumerated

above and we submit that claims 1, 9, 10 and 12 are not anticipated by Brown et al (US 5,769,887).

Aiba et al (US 6,221,096).

This reference teaches a self expanding stent which may be covered or uncovered but which is placed temporarily into the body but never actually released from wires which extend to outside the body. The wires (15) are welded or brazed to the elastic rings (14) (column 4 lines 3 to 7) so the portion 13 cannot be considered of as a series of stents linked together by flexible links. We further note that Aiba either teaches an entirely covered stent or an uncovered stent it does not teach a combination of these.

Again the reference Aiba et al does not teach or suggest the set of three essential items as claimed.

Further, neither the reference Brown et al nor the reference Aiba et al teach the uses of sutures a flexible links between stents in the uncovered portion. The Examiner appears to have understood the reference to sutures in claims 19 and 20 to refer to the connection of the graft to the self expanding stents but claims 19 and 20 refer to the suture being used to form the flexible links in the uncovered portion as is illustrated in Figure 6 and claimed in claims 19 and 20.

We note, too, that the Examiner has not located any reference in either Brown et al or Aiba et al to a spiral stent as illustrated in Figure 7 and claimed in Claim 23.

We submit that the features of claims 2, 5, 6, 8, 17 to 20, 22 and 23 which are not taught or suggested by Brown are also not taught of suggested in Aiba and hence we submit that claims 2, 5, 6, 8, 17 to 20, 22 and 23 are patentable under 35 USC 103(a) over Brown et al (US 5,769,887) in view of Aiba et al (US 6,221,096).

Greenberg et al (US 2002/0198587).

The reference Greenberg teaches a series of stents stitched to a graft

material tube and a single uncovered stent. There is no teaching of uncovered stents linked together by flexible links. We submit that the features of claims 7 and 11 which are not taught or suggested by Brown are also not taught of suggested in Greenberg and hence we submit that claims 7 and 11 are patentable under 35 USC 103(a) over Brown et al (US 5,769,887) in view of Greenberg (US 2002/0198587).

We further submit that the features of claim 21 which are not taught or suggested by Brown and Aiba et al are also not taught of suggested in Greenberg and hence we submit that claim 21 is patentable under 35 USC 103(a) over Brown et al (US 5,769,887) in view of Aiba et al (US 6,221,096) and further in view of Greenberg (US 2002/0198587).

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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Date: June 30, 2008

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